

DETAILED ACTION

Claim Objections

1. **Claim 16** is objected to because of the following informalities: There is a lack of antecedent basis. **The tip mentioned in Claim 16 is not present in either claim 12 or 13, the two claims that it is dependent upon.** Appropriate correction is required.
2. **Claims 2 and 13** are objected to because of the following informalities: the word "be" has been omitted from the phrases "configured to ___ coupled to said implantable pump." Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 6-9, 11 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by **Scott et al. (US Patent 5316246)**

Regarding **Claim 1**, **Scott et al.** discloses a catheter loop manager comprising a retainer element (10) configured to associate (12) with an implantable pump (Since the device is capable of associating with an implantable pump) and to releasibly hold (11) a loop of catheter. (Fig. 1A)

Regarding **Claim 2, Scott et al.** discloses the catheter loop manager of claim 1, wherein said retainer element (10) is configured to be coupled (12) to said implantable pump and to hold said loop (31A, Figure 3B) of said catheter adjacent to said implantable pump.

Regarding **Claim 3, Scott et al.** discloses a retainer body (10) and a tip portion (13) coupled to a front end thereof, said tip portion configured to engage a catheter connector on said implantable pump (The device is able engage the catheter connector by simply coming into contact with it), said retainer body configured to hold (11) said loop (31A) of said catheter.

Regarding **Claim 4, Scott et al.** discloses an internal channel (11), said channel configured to hold said loop of said catheter therein.

Regarding **Claim 6, Scott et al.** discloses a catheter loop manager apparatus comprising a retainer element (10, Fig. 1A) configured to couple (12) to an implantable pump and releasibly hold (11) a loop (31A, Fig. 3B) of catheter adjacent to said implantable pump.

Regarding **Claim 7, Scott et al.** discloses an elongated retainer body (10) having an elongated channel (11) extending there through, said channel configured to hold said loop (31A) of catheter.

Regarding **Claim 8, Scott et al.** discloses a tip portion (13) joined to a first end of said elongated retainer body, said tip portion configured to engage (engagement is performed by simply coming in contact with the catheter connector, so device is configured to perform this task) a catheter connector on said implantable pump.

Regarding **Claim 9, Scott et al.** discloses a bore (15), said bore configured to fit over said catheter connector (the bore is capable of fitting over a catheter connector) and allow an end of said catheter to couple to said connector.

Regarding **Claim 11, Scott et al.** discloses the catheter loop manager apparatus of claim 6, wherein said retainer element includes at least one lateral groove (11, Fig. 1A) configured to accommodate a suture.

Regarding **Claim 18, Scott et al.** discloses a method for managing a service loop of catheter in association with an implantable pump, comprising:

- (a) providing a retainer element (10),
- (b) affixing a catheter end (23) to a connector on said pump (21); and
- (c) drawing an excess portion of catheter into said retainer element to form a catheter loop therein (31A).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 5, 10, and 12-17, 19, 20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Scott et al.** in view of **Fowler et al. (US Patent 6146144)**

Regarding **Claims 5, 10, 12, and 22**, the device of **Scott et al.** discloses the invention claimed above except for the pull tool.

However, **Fowler et al.** teaches a pull tool for use in manipulating yarn through a mesh. The pull tool (20, Fig. 3) is able to releasibly engage (21) a flexible tube shaped object.

Since the marketplace reflects the reality that applying tools that assist processes, in particular relating to passing cord-like members through openings, is commonplace, it would have been obvious to one of ordinary skill in the art of loop management to modify the device as shown in **Scott et al.** with the hook tool as shown in **Fowler et al.**, in order to gain the commonly understood benefits of such adaptation, such as making the device easier to use.

Regarding **Claim 13**, the device of **Scott et al.** as modified by **Fowler et al.** further discloses the ability of the retaining element to be coupled to an implantable pump (12, Fig. 1A, **Scott et al.**).

Regarding **Claim 14**, the device of **Scott et al.** as modified by **Fowler et al.** discloses the elongated body (10), and the geometry of the tip portion (13).

Regarding **Claim 15 and 17**, the device of **Scott et al.** discloses the arcuate surface. (12, Fig. 1A) It further discloses the lateral groove. (11, Fig. 1A)

Regarding **Claim 16**, the device of **Scott et al.** discloses the bore (15) configured to fit over a catheter connector that allows a catheter end to affix to say catheter connector.

Regarding **Claim 19**, **Scott et al** discloses coupling said retainer element to said pump. (Device is capable of this action)

Scott et al. fails to disclose the specific wording of this action

However, **one of ordinary skill in the art at the time of the invention** would know to use a device that is capable of coupling to a pump to simply connect it to a pump.

Thus, it would have been obvious to a person of ordinary skill in the art to try coupling the device of **Scott et al.** in an attempt to provide an improved catheter loop manager, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp.

Regarding **Claim 20**, **Scott et al.** discloses the invention claimed above except for withdrawing said catheter loop from said retainer element after depletion of said implantable pump.

However, **one of ordinary skill in the art at the time of the invention** would know to detach a pump once it was depleted and not providing any beneficial function.

Thus, it would have been obvious to a person of ordinary skill in the art to try detaching the pump form the loop manager of **Scott et al.** in an attempt to provide an improved loop manager, as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp. In turn, because the method as

claimed has the same properties predicted by the prior art, it would have been obvious to complete this next step.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Scott et al.** in view of in view of **Fowler et al. (US Patent 6146144)**, as applied to claims above, further in view of **Lermon et al. (US Patent 6572587)**.

Regarding **Claim 21**, the device of **Scott et al., as modified by Fowler** fails to disclose the use of a suture to secure the implantable pump and retaining element.

However, **Lermon** teaches that implantable pumps and catheters have been typically sutured to ensure that migration won't occur. (Column 1, lines 43-50)

Scott et al.'s invention, as modified by Fowler, discloses the claimed invention except for the use of a suture to retain the implant. **Lermon** teaches that suturing implantable devices, specifically ones that involve implantable pumps, is known in the art. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to suture the loop manager as taught by **Lermon**, since **Lermon** states at column 1, lines 43-50 that such modification would make the implant more effective. Thus, it would have been obvious to one of ordinary skill in the art to apply the step of suturing an implant as taught in **Lermon**, to improve the loop manager of **Scott et al.** for the predictable result of restraining the implanted device.

Discussion of Cited but not Applied Prior Art

Teissen-Simony (US Patent 5522803) discloses a catheter connecting device for use with pumps.

Dragon (US Patent 5236143) discloses a catheter tubing manager.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian K. Holloway whose telephone number is 571-270-3862. The examiner can normally be reached on 8-5, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell L. McKinnon can be reached on 571-272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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